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REMARKS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of three months of the period for response to the Office Action. The prescribed fee is enclosed.

The withdrawal of the prior rejections under 35 USC 112, second paragraph as being indefinite, and under 35 USC 102(b) as anticipated by either Barber et al reference and the Baier et al reference, is gratefully acknowledged.

The Examiner maintained rejection of claims 1 to 4, 27 and 28 under 35 USC 103(a) as being unpatentable over Barber (USP 4,950,480) in view of Skea. Reconsideration is requested having regard to the following discussion.

The Barber '480 patent discloses the provision of anti-class II monoclonal antibodies coupled to antigens to target class II bearing antigen-presenting cells to bring about engagement of both the B and T cell components of an immune response. This brings about an enhancement of the immunotargeting of the antigen, in the absence of conventional adjuvants.

In this system, a biotin-streptavidin based interaction was used to bind the antibody and antigen. However, as specified in the disclosure, there are inherent disadvantages with such chemical coupling techniques, such as yield (about 20%) and also the variability factor between different preparations. In such procedures, there is no adequate control on the amounts of coupled peptides as well as the exact location of the reaction.

By way of contrast, the applicants' employ a recombinant approach and provide a recombinant conjugate antibody molecule. By using the recombinant approach, the difficulties of the biotin- streptavidin based interactions are overcome. In the present invention, each antigen moiety contained within the monoclonal antibody moiety in the recombinant conjugate antibody molecule is located exclusively at a preselected site.

In the Final Action, the Examiner referred to Figure 2(a) of Skea et al. This diagram simply contains a schematic of the reaction for linking the antigen to the monoclonal antibody using an avidin binder. This procedure also described under the heading "Materials and Methods", is the same as that disclosed in Example 1 of Barber '480 patent.

It is submitted that the teaching of Skea does not modify the teaching

of Barber et al with respect to the structure of the antibody-antigen conjugate. In particular, it is submitted that the combined teachings do not render obvious the provision of an antibody-antigen conjugate with the antigen located or a preselected site in the monoclonal antibody, nor how such a structure may be prepared.

Accordingly, it is submitted that claims 1 to 4, 27 and 28 are patentable over the applied prior art and hence the rejection thereof under 35 USC 103(a) as being unpatentable over the Barber '480 patent in view of Skea, should be withdrawn.

The Examiner maintained rejection of claims 1 to 4, 27 and 28 under 35 USC 103(a) as being unpatentable over Barber (USP 5,194,254) in view of Skea. Reconsideration is requested having regard to the following discussion. The text of the Barber '254 patent is the same as that of the Barber '480 patent. Hence the same arguments with respect to the relevance of the combination of cited prior art to the patentability of the claims discussed above with respect to the combination of Barber et al '480 and Skea et al apply equally with respect to this rejection and are incorporated herein by reference.

Having regard thereto, it is submitted that claims 1 to 4, 27 and 28 are patentable over the combination of Barber '254 and Skea and hence the rejection thereof under 35 USC 103(a) should be withdrawn.

The Examiner rejected claims 1 to 11, 27 and 28 under 35 USC 102(a) (it is believed the Examiner intended 35 USC 103 (a)) as being unpatentable over Barber (USP 4,950,480) in view of Baier et al. Reconsideration is requested having regard to the following discussion and the Declaration under 37 CFR 1.131 enclosed herewith.

The enclosed Declaration under 37 CFR 1.131 was submitted in copending Application 08/943,136, to demonstrate that, prior to April 1995, the date of the Baier et al reference, the applicants had possession of the invention, so that the Baier et al reference is not citable prior art under any section of 35 USC 102 and hence cannot be employed with the Barber et al '480 reference in any rejection of the claims.

Having regard to the above, it is submitted that claims 1 to 11, 27 and 28 are patentable over the combination of Barber '480 and Baier et al, and hence the rejection thereof under 35 USC 103(a) as being unpatentable over this

combination of prior art, should be withdrawn.

The Examiner rejected claims 1 to 11, 27 and 28 under 35 USC 102(b) (it is believed the Examiner intended 35 USC 103 (a)) as being unpatentable over Barber '254 in view of Baier et al. Reconsideration is requested having regard to the following discussion and the enclosed Declaration under 37 CFR 1.131. The submission of the Declaration removes Baier et al as citable prior art, as discussed above. Accordingly, it is submitted that claims 1 to 11, 27 and 28 are patentable over the combination of Barber '254 in view of Baier et al, and that the rejection thereof under 35 USC 103(a) as being unpatentable over the combination of prior art, should be withdrawn.

The Examiner rejected claims 1 to 11, 27 and 28 under 35 USC 102(a) as being unpatentable over Baier et al. As noted above, filing of the Declaration under 37 CFR 1.131 removes Baier et al as citable prior art and hence the rejection of claims 1 to 11, 27 and 28 under 35 USC 102(a) as being unpatentable over Baier et al, should be withdrawn.

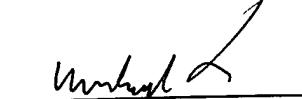
The Examiner rejected claims 1 to 11, 27 and 28 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 13 of US Patent No. 5,194,254 in view of Baier et al. Since Baier et al is not citable prior art, the rejection should be withdrawn.

It is noted that claim 5 has been rewritten in independent form. There remains no outstanding rejection of this claim, having regard to the above discussion and the removal of Baier et al as citable prior art. Accordingly, irrespective of the Examiner's position with respect to the patentability of claims 1 to 4 and 27 to 28 having regard to the combination of either Barber et al patents in view of Skea et al, it is submitted that claim 5 and the claims dependent thereon, are in an allowable form.

Entry of the Amendment After Final Rejection is requested in that the application is thereby placed in condition for allowance. In the event the Examiner considers one or more rejections to be outstanding, the Amendment nevertheless should be entered since the issues for appeal thereby are reduced and/or the claims are placed in better consideration for appeal.

It is believed that this application now is in condition for allowance and early and favorable consideration and allowance are respectfully submitted.

Respectfully submitted,

  
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